

Figure 1. Systemic Response to a Single Intranasal dose of Poly-ICLC in Rhesus Monkeys

Monkey #	Plasma Interferon titer	
	Baseline (Intl. U)	24 Hours (Intl. U)
CE 5 F	<3	200
CF 61	<3	200
CF 67	<3	700
CF4J	<3	700
CF 8F	<3	700
CF 5X	<3	<3
CF 45	<3	100
CF 4R	<3	200

Figure 2. Induction of Interferon in Rhesus Monkeys by 2mg/kg IV of Poly-ICLC as described in the present application (lot # RBP 10005) (Compare to table II in Levy'82, patent #4,349,538 treatment with 3mg/kg PICLC)

Monkey#	Hr. Bleed	IFN U/mL	IFN (Levy'82)
Rh H572	0 hr.	3	
Rh H573		<3	
Rh H574		<3	
Rh H578		<3	
Rh H572	8 hr.	7000	125-6000
Rh H573		7000	
Rh H574		7000	
Rh H578		2000	
Rh H572	24 hr.	700	0-125
Rh H573		300	
Rh H574		700	
Rh H578		200	

Figure 3. Particulate testing (clarity) of Poly-ICLC components and final product as described in the present application

	10-25 microns	>25 microns
Components:		
Poly I solution:	29.4/ml	.9
Poly C solution:	16/ml	1.7
Poly lysine solution:	94.8/ml	3.4
Carboxymethylcellulose solution:	199.6/ml	40.4
<u>Poly-ICLC</u> (improved method)	731/container	110
<u>Poly-ICLC</u> (older method)	>5,500	>500

Table 4: Percent Survival of Malignant Glioma Patients on Poly-ICLC

Survival	GBM 12 patients	AA 11 patients	AA (pf) 11 patients
1 yr	92% (50%†)	100%	100%
2 yr	50%	100% (50%†)	91%
3 yr	25% (2.2%†)	91%	82%
4 yr	17%	91%	82%
5 yr	8%	91%	73%
8 yr	8%	82%	36%

GBM = glioblastoma, AA = anaplastic astrocytoma, pf = progression free survival,

† = Expected survival on standard treatment with radiation and chemotherapy.

Group I: Poly-ICLC Plus AZT

"-" = Not done

Figure 6. Poly-ICLC Treatment of Progressive Multiple Sclerosis

CHRONIC-PROGRESSIVE MS							
SEX/ AGE	Mos. On PICLC	EDSS-E	AI-E	EDSS-L	AI-L	EDSS Change	Change Per yr.
F/29	128	7	8	8.5	9	1.5	0.1
F/35	82	8.5	9	10	9	1.5	0.2
M/25	27	7	8	10	9	3	1.3
M/42	189	5	5	7.5	6	2.5	0.2
F/39	136	8	9	9	9	1	0.1
M/28	12	6	5	5.5	3	-0.5	-0.5
M/22	45	7.5	7	8.5	9	1	0.3
F/61	121	6.5	5	8	5	1.5	0.1
M/49	164	6	4	6.5	6	0.5	0.0
F/39	114	8	8	8	8	0	0.0
M/46	13	9	9	7	7	-2	-1.8
M/25	42	7	6	7.5	8	0.5	0.1
F/59	26	5.5	4	6	3	0.5	0.2
M/41	25	8.5	9	8.5	9	0	0.0
F/62	6	7.5	8	7.5	8	0	0.0
M/23	10	5.5	3	4.5	3	-1	-1.2
F/50	85	6.5	6	7	6	0.5	0.1
F/41	60	6.5	6	9	9	2.5	0.5
F/35	126	8	8	8	9	0	0.0
MEDIAN	60	7.0	7.0	8.0	8.0	0.5	0.09
EXACERBATING PROGRESSIVE							
SEX/ AGE	Mos. On PICLC	EDSS-E	AI-E	DSS-L	AI-L	EDSS Change	Change Per yr.
F/36	4	9	9	3	2	-6	-18.0
F/34	35	5.5	2	6	3	0.5	0.2
F/26	68	4.5	0	5	2	0.5	0.1
F/55	85	4	2	3.5	2	-0.5	-0.1
F/35	84	3	2	3.5	3	0.5	0.1
M/42	28	6	4	6	4	0	0.0
F/25	63	9.5	9	4	2	-5.5	-1.0
M/22	3	8.5	9	6	6	-2.5	-10.0
F/14	57	8.5	9	4.5	2	-4	-0.8
F/54	9	8.5	9	8.5	8	0	0.0
F/29	12	5	3	1	1	-4	-4.0
F/34	25	5.5	3	5.5	3	0	0.0
F/17	83	9.5	9	3	2	-6.5	-0.9
MEDIAN	35	6.0	4.0	4.5	2.0	-0.5	-0.1

EDSS-E = Kurtzke Disability Status Score on Entry; EDSS-L = EDSS at Last examination; EDSS range from 1 (mild MS) to 9 (totally disabled)

AI-E = Ambulation Index on study entry; AI-L = AI at Last Examination

AI ranges from 1 (minimal disability) to 9 (bedridden)